UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BETTYE B. ALEXANDER, INDIVIDUALLY AND ON BEHALF OF THE ESTATE OF GARY E. ALEXANDER,	)	
Plaintiff,	)	
v.	)	**COMPLAINT**
	)	**and**
FRESENIUS USA, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, FRESENIUS USA MANUFACTURING, INC., and FRESENIUS USA MARKETING, INC.,	)	**JURY TRIAL DEMAND**
Defendants.		

PLAINTIFF'S ORIGINAL COMPLAINT AND JURY DEMAND

Plaintiff, Bettye B. Alexander, by and through the undersigned counsel, files this Complaint for damages against the Defendants named in the above-styled matter, and hereby asserts as follows:

I. STATEMENT OF VENUE AND JURISDICTION

1. This action seeks wrongful death damages under the Massachusetts Wrongful Death Statute and other applicable law on behalf of the Plaintiff and the Estate, heirs, beneficiaries, and next of kin of Gary E. Alexander, resulting from the use of NaturaLyte Liquid and GranuFlo Acid Concentrates (hereinafter collectively referred to as "GranuFlo" unless otherwise indicated) in his dialysis treatment, and his resulting Myocardial Infarction and death.

2. This court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332, in that there is complete diversity among the Plaintiff and the Defendants, and the amount in controversy exceeds $75,000.

3. A substantial amount of activity giving rise to the claims occurred in this District. Defendant Fresenius USA, Inc., is incorporated in Massachusetts, and the Defendants are each headquartered in Middlesex County, Massachusetts, and are engaged in significant business activities within this District. Therefore, venue is proper in this jurisdiction under 28 U.S.C. § 1391.

II. PARTIES

4. Decedent, Gary E. Alexander, at all relevant times hereto, was a resident of the Baton Rouge, Louisiana. Plaintiff, Bettye B. Alexander, the widow and representative of the Estate of Gary E. Alexander, is a resident of Baton Rouge.

5. Defendant, Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America, is a corporation organized and existing under the laws of New York, with its principal place of business at 920 Winter Street, Waltham, Middlesex County, Massachusetts. At all relevant times herein, Defendant was in the business of designing, manufacturing, marketing, promoting, labeling, and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates.

6. Defendant, Fresenius USA, Inc., is a corporation organized under the laws of the Commonwealth of Massachusetts, with a principal place of business at 920 Winter Street, Waltham, Middlesex County, Massachusetts. At all relevant times herein, Defendant was in the business of designing, manufacturing, marketing, promoting, labeling and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates.

7. Defendant, Fresenius USA Manufacturing, Inc., is a corporation organized under the laws of Delaware, with a principal place of business at 920 Winter Street, Waltham, Middlesex County, Massachusetts. At all relevant times herein, Defendant was in the business of designing, manufacturing, marketing, promoting, labeling and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates.

8. Defendant, Fresenius USA Marketing, Inc., is a corporation organized under the laws of Delaware with a principal place of business at 920 Winter Street, Waltham, Middlesex County, Massachusetts. At all relevant times herein, Defendant was in the business of designing, manufacturing, marketing, promoting, labeling and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates.

9. Defendants may be referred to collectively as "Defendants" or "Fresenius".

III. FACTUAL BACKGROUND

10. Defendants are involved in the worldwide design, development, manufacturing, marketing and sale of GranuFlo and accompanying equipment, services and products. Defendants generate revenue by selling their line of dialysis products to some 1800 Fresenius dialysis clinics, and another 1500 non-Fresenius clinics, throughout the United States. Defendants also sell a complete line of products promoted and used for 'at-home' dialysis treatment.

11. Defendants' products are used for Hemodialysis, a method of treatment for persons diagnosed with acute renal failure or chronic (end-stage) renal disease where conservative measures have failed. Hemodialysis is often referred to as an "artificial kidney". Hemodialysis attempts to perform the function of human kidneys by filtering and removing waste, extra fluid, and electrolytes from the blood. This process involves continuously cycling

blood directly from the patient, putting it through a dialysis machine that utilizes both a dialysate solution and a filtering device, and then returning the "cleansed" blood back to the body.

12. Many dialysis patients suffering from renal disease or failure often present for hemodialysis in a state called metabolic acidosis. This means that there is too much acid built up in the blood because the kidneys could not remove the excess. The resultant acid/base imbalance puts the patient into a state of acidosis. Dialysis aims to correct this acid/base imbalance through the use of a base, or bicarbonate -- a bicarbonate dialysate -- which acts then as a pH buffer to neutralize the metabolic acidosis. In effect, the bicarbonate neutralizes or buffers the excessive acid.

13. Another known result of renal failure is that the body's ability to produce electrolytes, such as calcium, potassium, and magnesium is reduced, creating an electrolyte imbalance. When these same electrolytes are, therefore, introduced into the blood during the hemodialysis process, they combine with bicarbonates to create an insoluble substance.

14. An acid concentrate must then be added to the bicarbonate dialysate to keep the needed minerals in solution and prevent this from occurring. GranuFlo is an acid concentrate.

15. In 2003, Defendants filed an application pursuant to section 510(k) of the Food and Drug Act for approval to market its concentrated dialysis product, later marketing under the name NaturaLyte GranuFlo Dry Acid Concentrate, or GranuFlo. In its application, the Defendants claimed that their concentrated dialysis product was substantially equivalent to previously-approved Fresenius dialysates. As stated in its application to the FDA, the new concentrated dialysis was intended to be used in three-stream hemodialysis machines, calibrated for acid and bicarbonate concentrates. In a three-stream dialysis machine, dialysate is made by mixing water with both a bicarbonate (base) concentrate and an acid concentrate, in specified

amounts. The dialysis process delivers the needed electrolytes, while also taking away waste products, mimicking the work of the natural kidney.

16. Physicians, typically nephrologists, prescribe a specific amount of bicarbonate to be given to their dialysis patients. That dosage is determined by the patient's blood serum level. When the acid mixture and the bicarbonate combine to form dialysate, a chemical reaction takes place and the added organic acid consumes an equivalent amount of bicarbonate in the final dialysate solution. The loss of bicarbonate is balanced by an equal gain in acetate. Acetate, a bicarbonate precursor, is rapidly converted to bicarbonate by the liver.

17. As such, if the prescribed bicarbonate concentration used to form dialysate is 37 mEq/L, and the acid concentration is 4 mEq/L from acetic acid, the reaction would produce 33 mEq/L of bicarbonate, and 4 mEq/L of acetate. After the acetate is metabolized by the liver to generate bicarbonate, the patient would still receive 37 mEq/L of bicarbonate, the prescribed amount.

18. However, a different reaction takes place when the acid used to form the dialysate is sodium diacetate, because sodium diacetate is composed of equal parts acetic acid and sodium acetate. GranuFlo contains sodium diacetate. When GranuFlo combines with bicarbonate to make dialysate, the acetic acid, as shown above, consumes an equal amount of bicarbonate and produces an equal amount of acetate, a bicarbonate precursor, so that the amount of bicarbonate stays the same. But here, the sodium acetate does not consume an equal amount of bicarbonate. Instead, the sodium acetate enters the bloodstream and, because it also is a bicarbonate precursor, is metabolized by the liver, also increasing the amount of bicarbonate delivered during dialysis. This in turn results in bicarbonate in the bloodstream being *over* the prescribed amount; in effect, a bicarbonate overdose.

19. In other words, GranuFlo contributes 4 mEq/L of acetic acid and 4 mEq/L of sodium acetate to the final dialysate solution. Because sodium acetate is a bicarbonate precursor and does not consume an equal amount of bicarbonate, it enters the bloodstream and is quickly metabolized, increasing the total buffer received to 4 mEq/L in excess of the prescribed amount. This excess bicarbonate buffer may cause metabolic alkalosis, a condition of having too much base (alkali) in the blood.

20. This metabolic alkalosis correlates with an increased risk of cardiopulmonary arrest ("CP Arrest") and sudden cardiac death or stroke during or after dialysis treatment.

21. Defendants began marketing and distributing the current formulation of its dry concentrated dialysate in 2003 using the trade name NaturaLyte GranuFlo Dry Acid Concentrate. It remains on the market today, albeit under a March 29, 2012 Class I Recall status obligating the Defendants to notify the public about the problems associated with calculating, delivering, and controlling bicarbonate levels when GranuFlo is used during the dialysis process.

22. In marketing GranuFlo, Defendants have consistently represented that GranuFlo was "[s]afe for … patients", and that utilizing dry sodium diacetate "eliminates the need for hazardous liquid glacial Acetic Acid, making GranuFlo the safest dry acid product."

23. Conversely, the dangers posed when bicarbonate levels are elevated to create metabolic alkalosis were known to the medical community by at least 2004, specifically, that metabolic alkalosis increases the risk of cardiopulmonary arrest. The Defendants knew or should have known of these dangers and the increased risk to patients.

24. The American Journal of Kidney Diseases published an article entitled, "Association of Pre-dialysis Serum Bicarbonate Levels with risk of Mortality and Hospitalization in the Dialysis Outcomes and Practice Patterns Study (DOPPS)" (2004). The

study found that patients with increased pre-dialysis metabolic alkalosis levels were more likely to experience a heart attack or sudden cardiac death if the bicarbonate prescription was not lowered. Defendants knew of these increased pre-dialysis levels in their patient population.

25. Since GranuFlo is comprised of both acetic acid and sodium diacetate, which is converted by the liver into bicarbonate, dangerously increased bicarbonate levels were evident, levels beyond the levels prescribed by a patient's physician. Again, it was shown that patients treated with GranuFlo receive, approximately, 4 mEq/L more bicarbonate in their treatment than intended by their prescription. Based on the knowledge readily available and known as early as 2004, Defendants knew or should have known of the increased risk of metabolic alkalosis and its consequences were tied to the use of GranuFlo.

26. Yet, it was not until November 4, 2011, and then, only in an internal memo to its own physicians and clinics, that Defendants disclosed and detailed their problem of metabolic alkalosis with Granuflo usage. Despite this previous knowledge, the Defendants failed to inform physicians that GranuFlo increases the level of bicarbonate in patients. This failure to inform physicians and healthcare providers of the need to reduce the bicarbonate prescribed to patients undergoing dialysis with GranuFlo allowed the dangerous effects of using GranuFlo to continue, unabated.

27. Defendants were aware GranuFlo caused dangerously elevated bicarbonate levels. In or about 2004, Defendants conducted a retrospective study of dialysis patients converted to GranuFlo up to April 2003, and found higher than normal post-dialysis bicarbonate levels as a result of the use of GranuFlo. In a May 17, 2006 patent application assigned to Defendants and referencing a provisional application filed exactly one year earlier, the application details an invention which takes into account "a contribution of bicarbonate resulting from metabolism of

acetate contained in an acid dialysate constituent." Accompanying the application is a diagram of Defendants' dialysis machine settings when using GranuFlo. The diagram reveals the extra contribution of 4 mEq/L of bicarbonate to the overall amount of buffer.

28. Defendants also knew that dialysis machines subject to this patent required special instructions for using GranuFlo, due to the effect of delivering dangerously high bicarbonate levels associated with the concentrated GranuFlo dialysate. Communications during this period show that Defendants knew the dialysis machines required additional labeling because of the danger of inducing metabolic alkalosis. For example, Defendants' dialysis machines denote a "halving of the Acetate Value when entering the value in the operator settlings in preparation for patient treatment", and Defendants' employees were being advised starting in 2008 to reduce the amount of bicarbonate in dialysis treatment by manipulating the dialysis machine settings. Defendants only disclosed this information internally to certain employees, but chose not to inform the nephrology and medical dialysis community at large.

29. In April, 2009, a dialysis conference was held in Boston entitled, "ESRD: State of the Art and Charting the Challenges for the Future." Dr. Raymond Hakim, M.D., Ph.D., who at the time was Chief Medical Officer for Fresenius, served on the Steering Committee for the conference. Other employees of the Defendants were also present. At that conference, Cardiopulmonary arrest was deemed to be the No. 1 ranking cause of death for dialysis patients, accounting for 59% of cardiovascular-related deaths among dialysis patients.

30. Around this time, Defendants were revising the dialysis machine manual used by operators, including the 2008T Model. The revisions clearly instructed its users as follows:

> **"When entering the Acetate value for GranuFlo concentrate, only half of the listed value on the label should be entered. For example, if the label shows an Acetate**

value of 8, then only enter 4." (2008T Machine Operator's Manual P/N 490122 Rev E Copyright 2008-2010).

31. From 2008 through 2010, Defendants continued to follow a of course irresponsibility, failing to provide adequate notification of the dangers inherent in Granuflo's use, and of the necessity to "halve" acetate levels when setting the parameters on dialysis machines prior to dialyzing patients. To the extent the Defendants did provide such information, they did so in a manner inconsistent with their responsibilities as a manufacturer, and with the obligations inherent in their earlier 510(k) filing with the FDA to market GranuFlo. Furthermore, Defendants' actions were such as to avoid general dissemination of necessary warnings and instructions and problems associated with its products. Defendants' failure to fully and forthrightly inform and warn the medical/dialysis and regulatory community severely and negatively impacted patient health and safety of innumerable dialysis patients including, in the case of Gary E. Alexander and thousands of others, death.

32. Defendants then studied a number of their dialysis patients to determine how many suffered cardiopulmonary arrest and/or sudden cardiac death in certain of their clinics during 2010. The results were first reported in an Internal Memorandum to Fresenius Clinic Medical Directors and other Fresenius affiliated health care providers on November, 4, 2011.

33. "RE: Dialysate Bicarbonate, Alkalosis, and Patient Safety" (hereafter, the "Internal Memo") details Defendants' case-control study comparing two hemodialysis patient groups, one whose patients had suffered cardiopulmonary arrest ("CP arrest") during treatment in a Fresenius clinic, and one whose patients had not. The first group included 941 dialysis patients in just 667 Fresenius clinics who, between January 1 and December 31, 2010, suffered cardiopulmonary arrest and sudden cardiac death during treatment as a result of alkalosis attributable to elevated bicarbonate levels associated with the use of GranuFlo. The results of

this study were conclusive: ***Dialysis patients with elevated pre-dialysis bicarbonate levels were 6 to 8 times more likely to suffer from a heart attack and sudden cardiac death than patients with lower bicarbonate levels.*** Notably, this study considered patient data from ***only*** 667 of Defendants' 1800 clinics, and from only a single year.

34. On November 4, 2011, Defendants made a limited release of that Internal Memo, sending it only to their own dialysis centers, stating that a "[r]ecent analysis performed using FMCNA [Fresenius Medical Care North America] hemodialysis (HD) patient safety data confirms that alkalosis is a significant factor associated with cardiopulmonary arrest (CP) in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. The major cause of alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration."

35. The Internal Memo went on to state that "[t]he current analysis determined that: '*orderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater risk of CP arrest and sudden cardiac death in the dialysis facilit'*... The bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate -- by *~8 mEq/L in the case of dialysate - prepared from GranuFlo (powder) or by ~4 mEq/L in the case of dialysate prepared from NaturaLyte (liquid)* -- since acetate is rapidly converted into bicarbonate by the liver." It concluded by recommending "*familiarize yourself with the formulation utilized in each of your facilities and consider lower bicarbonate prescriptions and adjust monthly depending on each patient's pre-dialysis bicarbonate level."* Meaning, at bottom, that GranuFlo adds 8 mEq/L of bicarbonate to the total bicarbonate prescribed to the dialysis patient.

36. The findings set forth in the Internal Memo were intentionally released *only* to dialysis facilities owned or controlled by Defendants and their doctors, and clinicians when warning of the significant risk of CP arrest and sudden cardiac death in dialysis patients using GranuFlo.

37. Defendants willfully and knowingly failed to notify, warn and/or instruct non-Fresenius dialysis clinics and operators to whom Defendants sold and marketed GranuFlo concentrate, nor did Defendants inform patients or the FDA of the purpose of the study, the need for the study, any post-market surveillance information it had involving the use of GranuFlo, or the results of this 2010 study.

38. It was not until March 29, 2012, after the FDA became aware of the dangers posed by GranuFlo and the number of instances of CPA, that Fresenius sent a notice (the "External Memo") to non-Fresenius clinics purchasing and using GranuFlo, stating that "NaturaLyte Liquid contains 4.0 mEq/L of acetate and GranuFlo contributes 8.0 mEq/L of acetate to the final dialysate; which in addition to bicarbonate, combine to the total buffer that the patient receives from the dialysate.... Since acetate is rapidly converted into bicarbonate by the liver, the bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate by ~8 mEq/L with dialysate prepared from GranuFlo (powder) or by ~4 m.Eq/L with dialysate prepared from NaturaLyte (liquid)."

39. The External Memo stated that *"[r]ecent analyses performed by FMCNA [Fresenius Medical Care North America] hemodialysis (HD) patient safety data confirms that alkalosis [high levels of bicarbonate] is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP*

arrest associated with pre-dialysis hypokalemia. A major cause of metabolic alkalosis is dialysis patients is inappropriate high dialysate total buffer concentration."

40. While the External Memo contained an "urgent product notification involving the NaturaLyte and GranuFlo powder product lines" and recommended that "clinicians exercise their best judgment regarding bicarbonate and total buffer base prescriptions for each patient", *it utterly failed to include the significant detail contained in the Internal Memo.*

41. At bottom, GranuFlo is defective and unreasonably dangerous for its intended use because it creates an unreasonably dangerous level of bicarbonate in the blood stream during dialysis, causing metabolic alkalosis and a corresponding substantial increase in the risk of cardiopulmonary arrest during dialysis treatment.

42. Defendants' dialysis machines are defective and unreasonably dangerous due to inadequate instructions and warnings when used with GranuFlo, in that the operator must "halve" the acetate level to account for the dangers inherent in Defendants' concentrated dialysates.

43. Defendants failed to properly warn of the dangers associated with the use of its products when manufactured and distributed and attempted to conceal those dangers from the public and the FDA up to and including March 29, 2012.

44. On March 29, 2012, the FDA reported Defendants' voluntary Class 1 recall of GranuFlo Acid Concentrate and NaturaLyte Liquid, which warned users of the heightened risk for low blood pressure, hypokalemia (low potassium levels), hypoxemia (low blood oxygen), hypercapnia (high carbon dioxide levels), and cardiac arrhythmia, possibly leading to sudden death.

45. A "Class 1" recall is the most serious type of recall, issued only in situations where a reasonable probability exists that use of the product at issue will cause serious health problems or death. Fresenius is currently under investigation by the FDA for its failure to warn of the risks associated with the use of Granuflo.

46. On April 15, 2011, the Deceased, Gary E. Alexander, went to his routine dialysis appointment at the Fresenius dialysis clinic at 4848 Mancuso Lane, Baton Rouge, Louisiana. Mr. Alexander had begun dialysis at the start of 2011. His dialysis treatment used GranuFlo. Mr. Alexander returned home after his three-hour dialysis treatment. He died later that night. The cause of death was stated as Myocardial Infarction.

47. Neither Mr. Alexander nor his healthcare providers were warned that GranuFlo is an unreasonably dangerous product, even when used exactly as the manufacturer intended. Defendants promoted, marketed and sold GranuFlo to Mr. Alexander and other consumers, and healthcare providers, and held out to the FDA that GranuFlo was safe for its intended purposes, as well as substantially equivalent to predicate devices that the FDA had previously approved for marketing prior to 1976. Mr. Alexander died as a result of receiving this unreasonably dangerous dialysate solution, which was unfit for the purpose it was designed, manufactured, marketed and sold.

48. GranuFlo was in a dangerous and defective condition at the time of its sale and delivery to Mr. Alexander. Its defective condition presented a danger to its foreseeable users and consumers, including Mr. Alexander, during ordinary and foreseeable use of the product.

49. As a result of his exposure to the defectively designed GranuFlo, Mr. Alexander went into cardiac arrest, resulting in his death due to Myocardial Infarction on April 16, 2011.

50. Mr. Alexander's Myocardial Infarction and subsequent death as a result of his exposure to GranuFlo were caused by, and were the direct and proximate result of, Defendants' breaches of warranty and negligence, and other wrongful conduct by Defendants by and through its agents, servants, workmen and employees, in any or all of the following respects, *inter alia*:

a. Failing to properly design, manufacture and test GranuFlo;

b. Selling, marketing and distributing GranuFlo in a dangerously defective condition;

c. Selling and distributing GranuFlo when it was not reasonably fit and suitable for its ordinary and intended purpose;

d. Failing to warn purchasers and users of GranuFlo of its defective condition before, during and after sale and delivery of the product;

e. Failing to properly inspect and test GranuFlo;

f. Marketing and selling GranuFlo when they knew or should have known of its inherent design defects;

g. Failing to properly and fully investigate prior incidents involving deaths related to the use of GranuFlo during dialysis;

h. Failing to correct known design and engineering deficiencies; and

i. Failing to timely, properly or adequately address defects in GranuFlo and implementing an untimely and inadequate Recall Campaign, which Defendants knew or should have known was deficient and not likely to correct the defects and dangers inherent in GranuFlo.

51. Defendants' fraud, concealment, and failure to disclose the defective nature of GranuFlo, the limited reach of its corrective action and recall campaign, and the failure to notify the families of patients that suffered sudden cardiac death during dialysis of the association

between GranuFlo and sudden cardiac death prevented Plaintiff from having actual or constructive knowledge any time before July 2012 (at the earliest) that the death of Mr. Alexander was caused by GranuFlo.

IV. CAUSES OF ACTION

COUNT I

Plaintiff's claim against the Defendants for BREACH OF WARRANTY

52. Plaintiff incorporates by reference all of the foregoing paragraphs as if they were fully restated herein.

53. The breach of warranty and wrongful conduct of Defendants in designing, manufacturing, marketing and distributing GranuFlo resulted in the Myocardial Infarction and subsequent death of Mr. Alexander.

54. As a direct and proximate result of Defendants' breach of warranty, Plaintiff is entitled to recover all allowable elements of damages under Massachusetts General Laws c. 229, § 6 and any other applicable law from the Defendants, in an amount that is just and appropriate to fully compensate Plaintiff and Decedent's estate, beneficiaries and next of kin for the wrongful death of Mr. Alexander, plus interest and costs.

COUNT II

Plaintiff's claim against the Defendants for NEGLIGENCE

55. Plaintiff incorporates by reference all of the foregoing paragraphs as if they were fully restated herein.

56. The wrongful conduct and negligence of Defendants in designing, marketing and distributing GranuFlo resulted in the myocardial infarction and subsequent death of Mr. Alexander.

57. As a direct and proximate result of Defendants' negligence, Plaintiff is entitled to recover all allowable elements of damages under Massachusetts General Laws c. 229, § 6 or any other applicable law from the Defendants in an amount that is just and appropriate to fully compensate Plaintiff and Decedent's estate, beneficiaries and next of kin for the wrongful death of Mr. Alexander, plus interest and costs.

COUNT III

Plaintiff's claim against the Defendants based on STRICT LIABILITY

58. Plaintiff incorporates by reference all of the foregoing paragraphs as if they were fully restated herein.

59. Defendants are strictly liable for designing, manufacturing and marketing a defective and unreasonably dangerous product, and for failing to warn, which were both proximate and producing causes of the personal injuries, death, and other damages suffered by Plaintiff and Decedent. It was reasonably feasible for Defendants to make available to the Plaintiff and dialysis treatment facilities information and adequate warnings regarding the risks associated with the use of their product, in light of the environment in which GranuFlo is used and provided to dialysis patients.

60. Defendants failed to correct known defects, and/or failed to recall, replace and/or provide post-sale warnings of the known defects and of the unreasonably dangerous nature of its product.

61. As a direct and proximate result of Defendants' actions, the Plaintiff is entitled to recover all allowable elements of damages under Massachusetts General Laws c. 229, § 6, or any other applicable law, from Defendants in an amount that is just and appropriate to fully

compensate Plaintiff and Decedent's estate, beneficiaries and next of kin for the wrongful death of Mr. Alexander, plus interest and costs.

COUNT IV

Plaintiff's Claim against Defendants under Mass. Gen. L. Ch. 93a Section 2, 9

62. Plaintiff incorporates by reference all of the foregoing paragraphs as if they were fully restated herein.

63. Defendants are engaged in trade or commerce in the Commonwealth of Massachusetts and was at all times relevant to the events described in this Complaint.

64. Defendants' violation of the implied and express warranty of merchantability constitutes a violation of G.L. c. 93A Section 2.

65. Defendants' willful and/or knowing withholding of safety information regarding GranuFlo constitutes a violation of the Massachusetts Consumer Protection Act, M.G.L. c. 93A Section 2, which prohibits 'unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Defendants knew or should have known from 2003, if not earlier during its own product research and development phase prior to filing for a 510(k) with the FDA, that there was an increased risk of hypotension, hypokalemia (low potassium levels), hypercapnia (high carbon dioxide levels), and cardiac arrhythmias associated with GranuFlo, and that the concentrated dialysate formula designed and manufactured with sodium diacetate would likely result in patients suffering from dangerously elevated bicarbonate levels, CP arrest, myocardial infarction, sudden cardiac death, stroke, and other life-threatening conditions or events.

66. Defendants failed to provide timely and adequate warnings and instructions to the medical/dialysis community and users/purchasers of GranuFlo of the risks, including

dangerously elevated bicarbonate levels, despite Defendants having actual knowledge of such risks from multiple sources of reliable information, including but not limited to their 2010 study identified in the Internal Memo which revealed CP arrest and sudden cardiac deaths in patients being treated with GranuFlo, their post-market surveillance information they tracked, and other events leading up to their deciding to conduct such a study as was referenced in the Internal Memo. Defendants should have known of the risks at the start of marketing GranuFlo in 2003 but failed to adequately study and evaluate the efficacy, chemical reaction and effect, or the consequences and dangers of using sodium diacetate as a chemical component of its dialysate GranuFlo.

67. The Defendants actively, knowingly, and fraudulently concealed their knowledge of GranuFlo's dangerous properties and life-threatening risks from the medical community and the regulatory body that reviewed Defendants' 510(k) intent to market GranuFlo application.

68. Defendants' fraudulent concealment and failure to warn, and to provide necessary and appropriate instructions and warnings, constitute a violation of c. 93A Section 9, as it is evidence of the Defendants' bad faith and unfair and deceptive practices.

69. As a direct and proximate result of Defendants' fraudulent, unfair and deceptive trade practices, and its willful or knowing failure to disclose and warn the dangers of using the Defendants' unsafe hemodialysis products, Plaintiff seeks damages, compensation and financial recovery as previously alleged and as permitted under G.L. c. 93, Section 9. The requisite statutory demand letter has been sent to Defendants.

COUNT V

NEGLIGENT MISREPRESENTATION

70. Plaintiff incorporates by reference all of the foregoing paragraphs as if they were fully restated herein.

71. At all relevant times, Defendants designed, tested, manufactured, packaged, marketed, distributed, promoted and sold GranuFlo.

72. At all relevant times, Defendants knew of the use for which GranuFlo was intended and expressly and/or impliedly warranted its products were of merchantable quality and safe and fit for such use.

73. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of GranuFlo, and their intentional dissemination of promotional and marketing information about GranuFlo for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the drugs.

74. Defendants negligently represented to Mr. Alexander and non-defendant physicians, and other persons and professionals on whom it was known by Defendants that patients would rely, as well as the public at large, that GranuFlo was safe to use and that the utility of the products outweighed any risk in use for their intended purposes.

75. Defendants negligently failed to disclose important safety and efficacy information, thereby suppressing material facts about GranuFlo, while having a duty to disclose such information, which duty arose from their actions of making, marketing, promoting, distributing and selling pharmaceutical products.

76. The false representations of the Defendants were negligently made in that GranuFlo in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the associated risks.

77. Defendants committed acts of negligent misrepresentation and negligent concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of GranuFlo.

78. Defendants knew or should have known that its representations and/or omissions were false. Defendants made such false, negligent representations and/or omissions with the intent or purpose that patients and any non-defendant physicians would rely upon such representations, leading to the use of these products by Decedent.

79. Defendants negligently misrepresented and/or omitted information with respect to GranuFlo in the following particulars, *inter alia*:

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo;

b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo;

c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo were used;

d. Failed to inform Mr. Alexander that GranuFlo had not been adequately tested to determine the safety and risks associated with using the products;

e. Misrepresented the safety of GranuFlo in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;

f. Misrepresented the risks associated with using GranuFlo;

g. Withheld and/or concealed and/or downplayed the evidence that the products were associated with an increased risk of serious injury and death;

h. Misrepresented that GranuFlo was as safe, or safer than, other similar products used in dialysis treatment;

j. Misrepresented information, regarding the true safety and/or efficacy of GranuFlo; and

k. Misrepresented through its labeling, advertising, marketing materials, publications, notice letters, and regulatory submissions that GranuFlo was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury and death associated with using GranuFlo.

80. Defendants negligently made affirmative misrepresentations and omitted material adverse information regarding the safety and effectiveness of GranuFlo.

81. Defendants made these misrepresentations and omissions at a time when Defendant knew or had reason to know that GranuFlo had defects, was unreasonably dangerous, and was not what Defendant had represented to the medical community, the FDA and the consuming public, including Mr. Alexander.

82. As a direct and proximate consequence of Defendants' negligence, Plaintiff and Decedent sustained injuries and damages alleged herein.

COUNT VI

FRAUDULENT MISREPRESENTATION AND CONCEALMENT

83. Plaintiff incorporates by reference all of the foregoing paragraphs as if they were fully restated herein.

84. At all relevant and material times, Defendants represented and expressly and impliedly warranted that GranuFlo products were safe, of merchantable quality, and fit for use in dialysis treatment.

85. Defendants' superior knowledge and expertise, its relationship of trust and confidence with doctors, operators of dialysis clinics, hospital-based dialysis units, and the public, its specific knowledge regarding the risks and dangers of GranuFlo and its intentional dissemination of promotional and marketing information about GranuFlo for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the products.

86. Defendants fraudulently misrepresented and concealed information which Defendants knew would be relied upon, including that GranuFlo was safe for use in dialysis treatment and that the utility of using this product outweighed any risk associated with its use.

87. Defendants failed to disclose to the FDA, Mr. Alexander, and non-Defendant physicians, important safety, efficacy, equivalence, and injury information, thereby suppressing material facts about the products, while having a duty to disclose such information.

88. These false representations were fraudulently made, in that the subject product in fact caused injury, was unsafe, and the benefits of the products were far outweighed by the risks associated with its use.

89. Defendants made false representations regarding the safety of GranuFlo with the intent or purpose that Decedent and the non-defendant healthcare providers involved in providing dialysis treatment to Decedent, would rely upon such representations, leading to the use of GranuFlo. Defendants knew or should have known that their representations and omissions were false.

90. Defendants committed acts of intentional misrepresentation and intentional concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of GranuFlo, in the following particulars, *inter alia*:

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo;

b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo;

c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo was to be used;

d. Failed to inform Decedent that GranuFlo had not been adequately tested to determine the safety and risks associated with using the products;

e. Misrepresented the safety of GranuFlo in the products' labeling, advertising, marketing materials, publications, notice letters, and/or regulatory submissions;

f. Misrepresented the safety, efficacy of GranuFlo and its substantial equivalence to predicate products as pertaining to its intended use, technological characteristics, design features, and materials and performance testing in its summary of safety and effectiveness for GranuFlo to the FDA pursuant to its 510(k) submission;

g. Misrepresented the risks associated with using GranuFlo;

h. Withheld, concealed, and/or downplayed the information, research and evidence that the products were associated with an increased risk of serious injury and/or death;

i. Misrepresented that GranuFlo was as safe or safer than other similar products on the market for the same intended use in dialysis treatment;

j. Fraudulently concealed information about the safety of GranuFlo including information that the products were not safer than alternative dialysis products available on the market; and

k. Misrepresented information, regarding the true safety and efficacy of GranuFlo;

91. Defendants knew that these representations were false, yet they willfully, wantonly, maliciously and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of GranuFlo to consumers, including Decedent, and to the medical community. Defendants did so with malice.

92. Defendants made these misrepresentations with the intent that non-defendant doctors and patients, including Decedent, would rely upon them.

93. Defendants' misrepresentations were made with the intent of defrauding and deceiving Decedent, other consumers, and the medical community to induce and encourage the sale of GranuFlo.

94. Decedent and the non-defendant healthcare providers involved in the dialysis treatment provided to Decedent relied upon the misrepresentations of the Defendants.

95. Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Decedent.

96. Defendants made affirmative misrepresentations and fraudulently concealed material adverse information regarding the safety and effectiveness of GranuFlo.

97. Defendants misrepresented and actively concealed adverse information at a time when Defendants knew or had reason to know that GranuFlo were not as safe as what Defendants had represented to the medical community, the FDA and the consuming public, including Decedent.

98. Defendants omitted, suppressed and concealed material facts concerning the dangers and risk of injuries associated with the use of GranuFlo, including the increased risk of serious injury and death.

99. Defendants' purpose was to willfully ignore, downplay, avoid, and/or otherwise understate the serious nature of the risks associated with the use of GranuFlo in order to increase sales.

100. As a direct and proximate consequence of Defendants' gross negligence, willful, wanton, reckless, malicious and/or intentional acts, omissions, misrepresentations or otherwise culpable acts described herein, Plaintiff and Decedent sustained injuries and damages as alleged herein, and are entitled to punitive damages.

COUNT VII

PUNITIVE DAMAGES

101. Plaintiff incorporates by reference all of the foregoing paragraphs as if they were fully restated herein.

102. Defendants' conduct was malicious, willful, wanton and reckless, and/or grossly negligent.

103. Defendants had actual knowledge of the wrongfulness of their conduct. Defendants also understood the high probability that their conduct would result in injuries and death for dialysis patients, including Mr. Alexander.

104. Further, Defendants were grossly negligent. Their conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of the persons exposed to it. Defendants consistently put their own financial benefit above the lived of their consumers and patients like Mr. Alexander. As a result, Mr. Alexander and thousands more died.

105. Defendants' wrongful conduct was motivated solely by putting profits over patients' health. The unreasonably dangerous nature of Defendants' conduct, together with the high likelihood of injury resulting from the conduct, was actually known by Defendants and those making policy decisions on behalf of Defendants.

106. At all times, Defendants were acting in concert and/or as the agent of one another, so the conduct of one Defendant may be imputed to all. Here, all the Defendants actively and knowingly participated in the wrongful conduct described herein.

107. Putative damages are necessary in this case to both punish Defendants for their reprehensible conduct and deter others who might otherwise act similarly.

108. Discovery will further reveal the malicious, willful, wanton, and reckless conduct supporting Plaintiff's claims for punitive damages.

V. PRAYER

WHEREFORE, the Plaintiff demands judgment against the Defendants in an amount sufficient to fully and fairly compensate Gary E. Alexander's estate and his beneficiaries and next of kin for their injuries and damages, both compensatory and punitive, costs of this action, interest to the full extent allowed by law, attorney's fees, and for multiple damages under G.L. c. 93A, Section 9, and for all other just and proper relief.

PLAINTIFF DEMANDS TRIAL BY JURY ON ALL COUNTS.

Respectfully submitted,

Bettye B. Alexander, Individually and on Behalf of the Estate of Gary E. Alexander,

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By her attorneys,

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